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UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

MARX FORD, individually and as Successor in Interest to the Estate of Gennie Price, deceased; RODNEY FORD; MARVIN FORD; and MORRIS FORD, Plaintiffs, vs. REDWOOD SPRINGS HEALTHCARE CENTER; SPRUCE HOLDINGS, LLC; and DOES 1 to 50, inclusive, Defendants.	Case No. [Removal from Superior Court of California, County of Tulare Case No. VCU286614] **DEFENDANT'S NOTICE OF REMOVAL OF ACTION UNDER 28 U.S.C. §§ 1331, 1441, 1442(a)(1) and 1446** *[Filed concurrently with Civil Cover Sheet and Request for Judicial Notice and Exhibits thereto]*

TO THE CLERK OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF CALIFORNIA:

PLEASE TAKE NOTICE AND NOTICE IS HEREBY GIVEN THAT Defendant, SPRUCE HOLDINGS, LLC dba REDWOOD SPRINGS HEALTHCARE CENTER (erroneously sued and served as REDWOOD SPRINGS HEALTHCARE CENTER and SPRUCE HOLDINGS, LLC) ("Defendant") hereby removes this action from the Superior Court of the State of California, County of Tulare to the United States District Court for the Eastern District of California. Removal is based on federal officer jurisdiction and federal question jurisdiction pursuant to 28 U.S.C. §§ 1331, 1441, 1442 (a)(1), and

1446. Defendant reserves all defenses and objections to venue based on 42 U.S.C. § 247d-6d(e)(1).

In support of this Notice of Removal, Defendant states as follows:

I. STATEMENT OF THE CASE

1. On or about April 7, 2021, Plaintiff commenced this action in the Superior Court of the State of California for the County of Tulare entitled *MARX FORD, individually and as Successor in Interest to the Estate of Gennie Price, deceased; RODNEY FORD; MARVIN FORD; and MORRIS FORD v. REDWOOD SPRINGS HEALTHCARE CENTER; SPRUCE HOLDINGS, LLC; and DOES 1 to 50, inclusive;* Case No. VCU286614. Pursuant to 28 U.S.C. § 1446(a), true and correct copies of all process, pleadings and orders served on Defendant in the Superior Court action are attached as Exhibit A to Defendant's Request for Judicial Notice (hereinafter "RFJN").

2. Plaintiff, Marx Ford, individually and as successor-in-interest to the decedent, Gennie Price, alleges that Gennie Price, age 78, was a resident at a skilled nursing facility, Spruce Holdings, LLC, dba Redwood Springs Healthcare Center ("Redwood Springs"), during the time relevant to the Complaint. (See Exhibit A to RFJN, Complaint ¶ ¶ 7, 8.)

3. Plaintiff alleges that due to the wrongful acts and omissions of Defendant, Gennie Price became infected with COVID-19 during her residency at Redwood Springs. Specifically, Plaintiff alleges that, despite knowledge of the seriousness of COVID-19 and the rise of infections in Visalia, REDWOOD SPRINGS "failed to take appropriate safety measures, including the distribution and use of Personal Protective Equipment and monitoring employees and staff for COVID-19 symptoms." (Exhibit A to RFJN, Complaint ¶ 11.) Plaintiff further alleges that Redwood Springs became aware of the infection of employees and residents with COVID-19, but failed to immediately notify other employees and family members of the residents of the outbreak at the nursing home. (Exhibit A to RFJN, Complaint ¶ 11.) Plaintiff also alleges that the facility continued to require and encourage employees to enter the facility and continue to work within the facility despite reporting to the facility their own COVID-19 infection and/or related symptoms. (Exhibit A to RFJN, Complaint ¶ 11.) Additionally, Plaintiff alleges that Redwood Springs failed to provide staff with the proper disinfectant supplies to assist with the prevention of the spread of the virus within the facility and cross-contamination of infected versus non-infected residents. (Exhibit A to RFJN, Complaint ¶ 11.)

Plaintiff contends that Redwood Springs either did not implement certain safety procedures and protocols and/or whatever safety procedures they did implement, if any, Defendant negligently failed to follow/monitor them and/or disregard them. (Exhibit A to RFJN, Complaint ¶ 16.) These failed safety measures included: "1. Failure of REDWOOD SPRINGS to provide staff and others at the facility Personal Protective Equipment; 2. Failure of REDWOOD SPRINGS to require the staff and others while at the facility to use and/or monitor the use of Personal Protective Equipment; 3. Failure to adequately staff REDWOOD SPRINGS with personnel uninfected with COVID-19; 4. Failure to provide REDWOOD SPRINGS staff and others with adequate training; 5. Failure of Redwood Springs to monitor the health of persons and staff entering the facility for COVID-19 related symptoms and infection; 6. Failure to provide adequate cleaning supplies and failure to adequately clean and sanitize the facility; 7. Failure to provide adequate care and/or monitoring of elderly patients that were positive for COVID-19; 8. Failure to properly and adequately isolate infected and suspected infected residents from non-infected residents and prevent cross-contamination of the healthy elderly residents; 9. Failure to timely test Gennie Price and other residents and staff for COVID-19 in order to timely isolate and separate the infected individuals from non-infected individuals; and 10. Failure to adequately inform the family of Gennie Price of the COVID-19 infection that had permeated the facility and the true health condition of Gennie Price. (Exhibit A to RFJN, Complaint ¶ 16.)

Plaintiff further alleges that Defendant "intentionally and/or recklessly exposed decedent to COVID-19." (Exhibit A to RFJN, Complaint ¶ 38.) The Complaint states that, "The pattern of substandard care and neglect put [Gennie Price] at extremely high risk for infection of COVID-19 and resulting complications, including injury and death. (Exhibit A to RFJN, Complaint ¶ 41.) Plaintiff also alleges that Defendant knew or should have known that the failure to comply with standards, by "providing custodial care wherein infected workers lacked personal protective equipment and by not employing and overseeing reasonable policies and procedures for isolating residents and employees that either tested positive for, or were suspected to have COVID-19, away from uninfected residents and employees" put residents, including decedent, in peril of being infected with COVID-19. (Exhibit A to RFJN, Complaint ¶ 47.) The Complaint alleges that the failure to require the use of personal protective equipment and employ reasonable policies and procedures for isolating residents and employees that

either tested positive for, or were suspected to have COVID-19, away from uninfected residents and employees, exposed decedent to the high probability of exposure to COVID-19, resulting in injury and/or death. (See Exhibit A to RFJN, Complaint ¶ 48.) Additionally, Plaintiff alleges that Defendant made "financial decisions at the expense of the safety of their residents and employees when they decided to limit spending on cleaning/disinfectant supplies and personal protective equipment, including face masks, gloves and gowns." (Exhibit A to RFJN, Complaint ¶ 50.) Plaintiff also alleges that Defendant decided not to incur the expense of employing health non-infected staff and rather encouraged and required infected and/or suspected infected staff to go to work at Redwood Springs, resulting in Ms. Price being infected with COVID-19. (See Exhibit A to RFJN, Complaint ¶ 50.) Plaintiff alleges causes of action for Elder Abuse, Willful Misconduct and Wrongful Death. (See Exhibit A to RFJN.)

II. THE PROCEDURAL REQUIREMENTS FOR REMOVAL HAVE BEEN MET

4. Defendant Spruce Holdings, LLC, dba Redwood Springs Healthcare Center was served with the Complaint on April 29, 2021.

5. Defendant's Notice of Removal was filed by June 1, 2021 and is timely under 28 U.S.C. § 1446(b) as this Notice has been filed within thirty (30) days of the service of a copy of the initial pleading setting forth the claims for relief.

6. Removal to the United States District Court for the Eastern District of California is proper because the Complaint was filed in the Superior Court of the State of California for the County of Tulare, which is located within the jurisdiction of this District. *See* 28 U.S.C. § 1441(a); and 28 U.S.C. § 84(c)(2).

7. Pursuant to 28 U.S.C. § 1446(d), a copy of this Notice of Removal is being served on Plaintiff, and a copy is being filed with the Clerk of the Superior Court of the State of California for the County of Tulare.

III. JURISDICTION UNDER 28 U.S.C. § 1331 EXISTS BASED ON THE PREP ACT

8. This case is removable under 28 U.S.C. § 1441(a) on the basis of "original jurisdiction" because Plaintiff's Complaint asserts a claim "arising under" federal law within the meaning of 28 U.S.C. § 1331.

9. Plaintiff's Complaint alleges that due to the wrongful acts and omissions of Defendant, the decedent Gennie Price became infected with COVID-19 during her residency at Redwood Springs and died due to the virus on April 22, 2020. (See Exhibit A to RFJN, Complaint ¶¶ 1, 10, 11, 12, 13, 14, 15, 16, 17, 38, 41, 47, 48, 50, 52.)

10. Such allegations relate to Redwood Springs' administration or use of qualified pandemic products used to diagnose, mitigate, prevent, treat or cure COVID-19 or to limit the harm COVID-19 might otherwise cause, including personal protective equipment (facemasks, gloves, gowns, and goggles), NIOSH approved respiratory protective devices (N95 facemasks) and COVID-19 testing kits. Therefore, the claims fall under the Public Readiness and Emergency Preparedness Act, 42 U.S.C. §§ 247d-6d and 247d-6e (2006) (the "PREP Act"), the applicability of which presents a significant federal question relating to the ongoing national emergency and COVID-19 pandemic. As such, Congress provided an exclusive remedy for the substance of the allegations and relief sought in the Complaint, and federal law expressly preempts state law for purposes of federal question jurisdiction. *See* PREP Act, 42 U.S.C. §§ 247d-6d, 247d-6e.

11. The PREP Act, along with the Declaration of United States Health and Human Services ("HHS") Secretary (including all amendments thereto), are federal statutes that apply to healthcare providers and skilled nursing facilities, such as Redwood Springs, with respect to the administration and use of countermeasures to diagnose, treat, prevent and mitigate the spread of COVID-19.

12. As Plaintiff has alleged claims which are preempted under a federal statute, this Court has original jurisdiction pursuant to 28 U.S.C. § 1331, which provides that "[t]he district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." Federal courts have "jurisdiction to hear, originally or by removal from a state court, only those cases in which a well-pleaded complaint establishes either that federal law creates the cause of action *or* that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law." *Franchise Tax Bd. of State of Calif. v. Construction Laborers Vacation Trust for Southern Calif.*, 463 U.S. 1, 27-28 (1983); *Dennis v. Hart*, 724 F.3d 1249, 1253 (9th Cir. 2013); *Rivet v. Regions Bank of Louisiana*, 522 U.S. 470, 475 (1998).

13. While a plaintiff is ordinarily entitled to choose a state or federal forum, "a plaintiff may

not defeat federal subject-matter jurisdiction by omitting to plead necessary federal questions", i.e., "artful pleading." *Rivet v. Regions Bank of La.*, 522 U.S. 470, 475. "If a court concludes that a plaintiff has 'artfully pleaded' claims in this fashion, it may uphold removal even though no federal question appears on the face of plaintiff's complaint. The artful pleading doctrine allows removal where federal law completely preempts plaintiff's state-law claim." *Id.* "The artful pleading rule applies when Congress has either (1) so completely preempted, or entirely substituted, a federal law cause of action for a state one that plaintiff cannot avoid removal by declining to plead necessary federal questions, or (2) expressly provided for the removal of particular actions asserting state law claims in state court." *Romano v. Kazacos*, 609 F.3d 512, 519 (2d Cir. 2010) (internal citations and quotations omitted).

14. Complete preemption exists when the preemptive force of federal law is so powerful that it displaces any state law cause of action, and leaves room only for a federal claim for purposes of the "well-pleaded complaint" rule.[1] *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 63-64 (1987); *see also NASDAQ OMX Group, Inc. v. UBS Securities, LLC*, 770 F.3d 1010 (2d Cir. 2014). Complete preemption exists when (1) the statute relied upon by defendant as preemptive contains civil enforcement provisions within the scope of which plaintiff's state law claims fall; and (2) there is a "clear indication of Congressional intention to permit removal despite the plaintiff's exclusive reliance on state law." *Railway Labor Executives Ass'n v. Pittsburgh & Lake Erie R.R. Co.*, 858 F2d 936, 942 (3d Cir. 1988) citing *Franchise Tax Bd. of State of Calif. v. Construction Laborers Vacation Trust for Southern Calif., supra,* 463 U.S. at 24.

A. The PREP Act Generally

15. The PREP Act was enacted in December 2005, to encourage the development and deployment of covered countermeasures in response to public health emergencies. Congress has provided that the HHS Secretary "shall lead all federal public health and medical response to public health emergencies." 42 U.S.C. § 300hh. The PREP Act gives the HHS Secretary authority to issue a declaration recommending administration of specified countermeasures and providing liability

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[1] Federal jurisdiction requires that only one claim be identified as a federal question. *See* 28 U.S.C. § 1367 [supplemental jurisdiction]; *see also Franchise Tax Board v. Laborers Vacation Trust*, 463 U.S. 1, 13 (1983).

immunity to "covered persons" "against any claim of loss caused by or relating to the administration/use of such countermeasures and the management and operation of a covered countermeasures program. 42 U.S.C. § 247-6d(a)(1).

16. In enacting the PREP Act, 42 U.S.C. §§ 247d-6d and 247d-6e (2006), Congress has provided preemption and immunity for the claims and relief sought in Plaintiff's Complaint. With the PREP Act, Congress sought to alleviate liability concerns associated with delivering countermeasures to the public by providing protections for healthcare providers involved in the planning, distribution and dispensing such countermeasures. P. Binzer, *The PREP Act: Liability Protection for Medical Countermeasure Development, Distribution, and Administration, Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, Vol. 6, No. 4, 2008, at pg. 294. The liability immunity provided in the PREP Act ensures that healthcare providers such as HPHC are not subject to lawsuits which tax their time and energy, when such resources should be directed toward resident care.

17. The PREP Act provides liability protections for pandemic and epidemic products and their administration. The legislation empowers the Secretary of HHS to issue a declaration providing immunity for "covered persons" to suits and liability under federal and state law with respect to claims relating to the administration of a "covered countermeasure" during a health emergency. 42 U.S.C. §§ 247d-6d(a)(1). Specifically, 42 U.S.C. § 247d-6d(a)(1) provides as follows:

> Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

18. Section (b) of the PREP Act provides that if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, the Secretary may make a declaration setting forth that subsection (a) is in effect with respect to the manufacture, testing, development, distribution, administration or use of one or more Covered Countermeasures under conditions as the Secretary may specify in the Declaration or an amendment thereto. 42 U.S.C. § 247d-6d(b)(1) and (4).

19. The PREP Act further provides that, *"[n]o court of the United States, or of any State,*

shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection." 42 U.S.C. § 247d-6d(b)(7) (emphasis added). Thus, under the PREP Act, Congress has not only provided immunity to claims arising out of Covered Countermeasures, it has delegated regulatory authority to the HHS Secretary.

20. As Congress has expressly delegated the duty to apply and interpret the Act to the Secretary, the Declaration of the HHS Secretary (and any amendment thereto) are entitled to *Chevron* deference. Where Congress has expressly delegated interpretive authority to an agency, that agency's interpretative proclamations are controlling on the federal courts. *See Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-844 (1984).

21. Further, it can "be apparent from the agency's generally conferred authority and other statutory circumstances that Congress would expect the agency to be able to speak with the force of law when it addresses ambiguity in the statute or fills a space in the enacted law", especially where the agency's reasoning is valid. *United States v. Mead Corp.,* 533 U.S. 218, 228-229 (2001). As such, "a reviewing court has no business rejecting an agency's exercise of its generally conferred authority to resolve a particular statutory ambiguity simply because the agency's chosen resolution seems unwise … but is obliged to accept the agency's position if Congress has not previously spoken to the point at issue and the agency's interpretation is reasonable…." *Id.* at 229. (Internal citations omitted); *Chevron U. S. A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-44 (1984) ("a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.")

22. The Second Circuit in *Catskill Mountains Chapter of Trout Unlimited, Inc. v. Envtl. Prot. Agency*, 846 F.3d 492, 507 (2d Cir. 2017), emphasized the importance of judicial deference where agency action is sound and reasoned. Therein, the court explained that under *Chevron,* the first question is: "'whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'" *Id.* at 507, *citing Chevron*, 467 U.S. at 842–43. If the statutory language is silent or ambiguous, however, courts proceed to the second step, where "'the question for the court is whether the agency's answer is based on a permissible construction of the

statute'" at issue. *Id.*, citing *Chevron*, 467 U.S. at 843. If the agency's interpretation is not "'arbitrary, capricious, or manifestly contrary to the statute,'" *Id.*, *citing Chevron*, 467 U.S. at 844, the court will accord deference to the agency's interpretation so long as it is supported by a reasoned explanation, and "so long as the construction is "'a reasonable policy choice for the agency to make.'" *Id.*, *citing Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 986 (2005).

23. Here, HHS is charged with administering the PREP Act during a national public health emergency. Its interpretation that the PREP Act is a complete preemption statute is based on the framework of the PREP Act, including the purpose and scope of the Act as applied to the COVID-19 pandemic and the Act's exclusive federal remedial scheme. This interpretation is sound and reasonable, especially since other complete preemption and original jurisdiction statutes have analogous remedial schemes that involve both administrative and judicial remedies.

B. The Declaration of the HHS Secretary for the COVID-19 Pandemic and Advisory Opinions

24. On March 10, 2020, the HHS Secretary issued a Declaration invoking the PREP Act for the COVID-19 pandemic. The Declaration was effective as of February 4, 2020. 85 Fed. Reg. 15,198 (Mar. 17, 2020); (See Exhibit B to RFJN). The Secretary subsequently issued an Amended Declaration under the PREP Act, which was effective as of March 27, 2020. 85 Fed. Reg. 21,012 (Apr. 15, 2020); (See Exhibit C to RFJN). The Amendment added respiratory protective devices approved by NIOSH (National Institute for Occupational Safety and Health) as a covered countermeasure under the PREP Act. On June 4, 2020, the Secretary further amended the March 10, 2020 Declaration to clarify that covered countermeasures under the Declaration include qualified products that limit the harm COVID-19 might otherwise cause. This Amendment was effective as of February 4, 2020. 85 Fed. Reg. 35,100 (June 8, 2020); (See Exhibit D to RFJN).

25. On December 3, 2020, the HHS Secretary issued a Fourth Amended Declaration under the PREP Act and made this Amended Declaration effective as of February 4, 2020. 85 Fed. Reg. 79,190 (Dec. 9, 2020); (See Exhibit E to RFJN). The Secretary's Fourth Amended Declaration provides that "***COVID-19 is an unprecedented global challenge that requires a whole-of-nation response that utilizes federal-, state-, and local-distribution channels as well as private-distribution channels.***

Given the broad scale of this pandemic, the Secretary amends [Section VII of] the Declaration to extend PREP Act coverage to additional private-distribution channels . . . ." 85 Fed. Reg. at 79,194; (See Exhibit E to RFJN, pg. 12 (emphasis added)).

26. The Fourth Amended Declaration specifically provides that Section VII of the Declaration is amended to extend liability protection under the PREP Act to Covered Persons for Recommended Activities that are related to: "Covered Countermeasures" that are:

> i. Licensed, approved, cleared or authorized by the FDA (or that are permitted to be used under an Investigational New Drug Application or an Investigational Device Exemption) under the FD&C Act or PHS Act to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom; or
> ii. A respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be priority for use during a public health emergency declared under section 319 of the PHS Act to prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom. 85 Fed. Reg. at 79,194; (See Exhibit E to RFJN, pg. 12).

27. Secretary Azar's Fourth Amended Declaration further makes explicit that there can be situations where not administering a Covered Countermeasure to a particular individual can fall under the PREP Act. ***"Prioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive, can fall within the PREP Act and this Declaration's liability protections.***" 85 Fed. Reg. at 79,197; (See Exhibit E to RFJN, pgs. 13 (emphasis added)).

28. The Fourth Amended Declaration further provides that ***the Declaration is to be construed in accordance with the Department of Health and Human Services (HHS) Office of the General Counsel (OGC) Advisory Opinions on the PREP Act ("Advisory Opinions"). "The Declaration incorporates the Advisory Opinions for that Purpose***." 85 Fed. Reg. at 79,191; (See Exhibit E to RFJN, pg. 3 (emphasis added)). Thus, the Fourth Amended Declaration incorporates all OGC Advisory Opinions related to COVID-19 and the PREP Act into the Secretary's March 10, 2020 initiating Declaration. Thus, the OGC Advisory Opinions must be afforded *Chevron* controlling weight.

29. Crucially, as discussed more completely below, Amendment Four directly acknowledges the federal interests in cases which require interpretation and application of the PREP Act:

> COVID-19 is a global challenge that requires a whole-of-nation response. **There are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mfg.*, 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities.** 85 Fed. Reg. at 79,197; (See Exhibit E to RFJN, pgs. 13-14 (emphasis added)).

30. Amendment Four further explains:

> The world is facing an unprecedented pandemic. To effectively respond, there must be a **more consistent** pathway for Covered Persons to manufacture, distribute, **administer** or use Covered Countermeasures across the nation and the world. Thus, there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mfg.*, 545 U.S. 308 (2005), in having **a uniform interpretation of the PREP Act**. 85 Fed. Reg. at 79,194 (See Exhibit E to RFJN, pg. 26 (emphasis added)).

Thus, Amendment Four declares that the interpretation of the PREP Act is a matter of significant and substantial federal concern, and that removal of any case involving the interpretation of that Act is proper in accordance with the Supreme Court holding in *Grable*.

31. On January 8, 2021, the OGC issued additional controlling authority in the form of Advisory Opinion 21-01, which unequivocally confirms that: (1) the PREP Act is a "Complete Preemption" Statute which confers federal question removal jurisdiction under 28 U.S.C. § 1441(a); (2) the PREP Act is invoked by allegations like those in the Complaint, including alleged inaction or failure to act; and (3) as discussed in more detail below, federal jurisdiction is separately conferred in such cases under the doctrine articulated by the United States Supreme Court in *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mfg.*, 545 U.S. 308 (2005), because "ordaining the metes and bounds of PREP Act protection in the context of a national health emergency necessarily means that ***the case belongs in federal court.***" (Exhibit DD to RFJN (emphasis added).)

32. Advisory Opinion 21-01 unequivocally states, after providing an analysis of relevant case law, that "[t]he PREP Act is a 'Complete Preemption' Statute," because it establishes both a federal and administrative cause of action as the only viable claim, and vests exclusive jurisdiction in federal court. (Exhibit DD to RFJN.)

33. Advisory Opinion 21-01 rejects the notion that immunity under the PREP Act requires actual "use" of a covered countermeasure. Specifically, it provides that, "this 'black and white' view

clashes with the plain language of the PREP Act, which extends immunity to ***anything 'relating to'*** the administration of a covered countermeasure." (Exhibit DD to RFJN, pgs. 2-3 (emphasis added).)

34. Advisory Opinion 21-01 further provides that "[p]rioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive, can fall within the PREP Act and this Declarations liability protections. ***The Opinion states that there also can potentially be other situations where a conscious decision not to use a covered countermeasure could relate to the administration of the countermeasure."*** (Exhibit DD to RFJN, pgs. 2-3 (emphasis added).)

35. Additionally, Advisory Opinion 21-01 explains that "program planners" fall within the set of "covered persons" under the PREP Act and that "decision-making that leads to ***the non-use of covered countermeasures by certain individuals is the grist of program planning, and is expressly covered by PREP Act***." (Exhibit DD to RFJN, pg. 4 (emphasis added).)

36. Advisory Opinion 21-01 is binding on this court, as the HHS Secretary incorporated all HHS Advisory Opinions pertaining to COVID-19 into the PREP Act's implementing Declaration itself, and proclaimed that the Declaration "must" be construed in accordance with them. (See Exhibit E to RFJN.)

37. As confirmed in Advisory Opinion 21-01, when the PREP Act is triggered, complete preemption attaches. Indeed, "[t]he sine qua non of a statute that completely preempts is that it establishes either a federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both." (Exhibit DD to RFJN, pg. 2.) And the Fifth Amendment to Secretary Azar's Declaration, published on February 2, 2021, reiterates that "[t]he plain language of the Prep Act makes clear that there is ***complete preemption of state law***…." 86 Fed. Reg. 7,872, 7,874 (Feb. 2, 2021); (Exhibit CC to RFJN).

38. Here, Plaintiff's claims are preempted by the PREP Act. Under the PREP Act, Congress has provided an exclusive remedy and exclusive federal jurisdiction for the substance of the allegations and relief sought in the Complaint thereby preempting state law with respect to the claims raised in the Complaint. Moreover, Redwood Springs' administration of countermeasures, such as the use of facemasks and other PPE, and COVID-19 testing, to diagnose, treat, prevent or mitigate the spread of

COVID-19 which forms the basis of this action, presents a federal question under the PREP Act giving this Court original jurisdiction preempting the state claims asserted by Plaintiff in the Complaint.

C. Federal Question Jurisdiction is Proper Under the Doctrine of Complete Preemption Because the PREP Act Expressly Preempts Plaintiff's State Law Claims and Provides an Exclusive Set of Federal Remedies

39. On its face, Plaintiff's claims appear to sound in state law. However, Congress has already provided an exclusive federal remedy for Plaintiff's "claim for loss" under the PREP Act, in the form of a no-fault compensation program and an exclusive judicial cause of action for claims of "willful misconduct."

40. Complete preemption is "a jurisdictional rather than a preemption doctrine, [as it] confers exclusive federal jurisdiction in certain instances where Congress intended the scope of federal law to be so broad as to entirely replace any state-law claim." *Marin General Hosp. v. Modesto & Empire Traction Co.,* 581 F.3d 941, 945 (9th Cir. 2009). Complete preemption exists when the preemptive force of federal law is so powerful that it displaces any state law cause of action, and leaves room only for a federal claim for purposes of the "well-pleaded complaint" rule. *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 63-64 (1987). The Ninth Circuit has acknowledged that removal based on the complete preemption doctrine is appropriate where Congress has created an exclusive federal cause of action. *See In re Miles*, 430 F.3d 1083, 1088 (9th Cir. 2005).

41. The issue of whether federal question jurisdiction exists when a plaintiff asserts a claim in state law was addressed by the Supreme Court in *Beneficial Nat. Bank v. Anderson*, 539 U.S. 1 (2003). The Court explained:

> [A] state claim may be removed to federal court … when a federal statute wholly displaces the state-law cause of action through **complete pre-emption**. When the federal statute completely pre-empts the state-law cause of action, a claim which comes within the scope of that cause of action, even if pleaded in terms of state law, is in reality based on federal law. In the two categories of cases where this Court has found complete pre-emption … the federal statutes at issue **provided the exclusive cause of action** for the claim asserted and also **set forth procedures and remedies governing that cause of action**. *Id.* at 8 (emphasis added; internal citations and footnotes omitted).

42. There, the plaintiff brought an action for usury under state law, which was preempted by the usury provisions of the National Bank Act (12 U.S.C.A. §§ 85 and 86). The Court held that even though Congress did not explicitly provide for removal of preempted claims, the provisions collectively

"supersede[d] both the substantive and the remedial provisions of state usury laws and create a federal remedy for overcharges that is exclusive." *Beneficial Nat. Bank, supra,* at 11. Therefore, the Court held that federal question jurisdiction was proper under the "complete preemption" doctrine.

43. Since 2003, the doctrine of "complete preemption" has been applied by the lower courts to at least ten other statutes.[2] Circuit and district courts considering the issue have found "complete preemption" where a federal statute (1) expressly preempts state law and (2) creates an exclusive federal remedy for preempted state claims. *See, e.g., In re WTC Disaster Site*, 414 F.3d 352, 380 (2d Cir. 2005); *Spear Marketing, Inc. v. Bancorp South Bank*, 791 F.3d 586 (5th Cir. 2015); *Nott v. Aetna U.S. Healthcare, Inc.*, 303 F.Supp.2d 565 (E.D. Pa. 2004).

44. The Court in *Rachal v. Natchitoches Nursing & Rehabilitation Center, LLC*, 1:21-cv-334 (W.D. La. April 30, 2021), recently found that the PREP Act is a complete preemption statute. (RFJN Ex. "RR".) The *Rachal* Court found the PREP Act analogous to ATSSSA, which was passed following the September 11, 2011 terrorist attacks, as both statutes: (1) create an administrative no-fault compensation fund; (2) provide broad immunity from suit for certain entities/individuals; (3) create an exclusive federal cause of action for certain residual claims as the exclusive judicial remedy for damages; and (4) specifies an exclusive federal venue for suits brought under the federal cause of action. *Rachal*, at n. 3, citing *In re WTC Disaster Site*, 414 F.3d 352 (2d Cir. 2005).

45. The *Rachal* court concluded that Congress intended "that the PREP Act exclusively encompass 'claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure. [42 U.S.C.] § 247d-6d(a)(1). Accordingly, to

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[2] These include the Transportation Safety and System Stabilization Act (*In re WTC Disaster Site*, 414 F.3d 352 (2d Cir. 2005)); the Bankruptcy Code (*In re Miles*, 430 F.3d 1083 (9th Cir. 2005)); the Carmack Amendment to the Interstate Commerce Act (*see, e.g., Smallwood v. Allied Van Lines, Inc.*, 660 F.3d 1115 (9th Cir. 2011); the Interstate Commerce Commission Termination Act (*see, e.g., Elam v. Kansas City Southern Ry. Co.*, 635 F.3d 796 (5th Cir. 2011)); the Copyright Act (*see, e.g., Spear Marketing, Inc. v. BancorpSouth Bank*, 791 F.3d 586 (5th Cir. 2015)); the Federal Communications Act (*see, e.g., Bastien v. AT&T Wireless Services, Inc.*, 205 F.3d 983 (7th Cir. 2000)); the Federal Deposit Insurance Act (*Vaden v. Discover Bank*, 556 U.S. 49 (2009)); the Federal Railroad Safety Act (*see, e.g., Lundeen v. Canadian Pacific R. Co.*, 532 F.3d 682 (8th Cir. 2008)); the National Labor Relations Act (*see, e.g., Price v. Union Local 25*, 787 F. Supp. 2d 63 (D.D.C. 2011)); and the Securities Litigation Uniform Standards Act (SLUSA) (*see, e.g., Brockway v. Evergreen Intern. Trust*, 496 Fed. Appx. 357 (4th Cir. 2012)).

the extent Plaintiff's alleged loss [that] . . . arose out of, related to, or resulted from the administration . . . of a 'covered countermeasure,' this Court has federal question jurisdiction to apply the provisions of the PREP Act." Id.

46. In *Gilbert Garcia et al v. Welltower OpCo Group LLC*, 2021 WL 492581 *6 (February 10, 2021), Judge James V. Selna of the U.S. District Court for the Central District of California also ruled that the PREP Act is a complete preemption statute.

47. The PREP Act plainly satisfies both prongs of this analysis. First, the PREP Act clearly preempts any state law that runs afoul of the immunity granted thereunder. Under 42 U.S.C. § 247d-6d(a)(1), a "covered person" is afforded broad immunity "from **suit and liability** under Federal **and State law**" for "**all claims for loss** caused by, arising out of, relating to, or resulting from" the "administration" or "use" of a "covered countermeasure" if the Secretary of the HHS issues a declaration to that effect—which he has. (Emphasis added.) The PREP Act also expresses its clear intention to preempt state control of the issues raised, and explicitly provides as follows:

> During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—
> (A) is different from, or is in conflict with, any requirement applicable under this section; and
> (B) relates to the . . . distribution, sale, donation, purchase . . . or the prescribing, dispensing or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter. . . 42 U.S.C. § 247d-6d(b)(8).

48. The second prong of the *Beneficial* analysis is also met. The PREP Act clearly establishes a set of exclusive federal remedies for any claim preempted, and the procedures applicable to such actions. Under 42 U.S.C. § 247d-6d(d)(1) "the sole exception to the immunity from suit and liability of covered persons . . . shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct." The statute further sets forth the procedures for suit. Pursuant to the provisions set forth in subsection (e)(1), titled "**Exclusive Federal Jurisdiction**," any action for willful misconduct must be filed in the U.S. District

Court for the District of Columbia. Such claims are also subject to heightened pleading requirements, including requirements for pleading with particularity, verification of and submission of a physician declaration in support of the complaint. 42 U.S.C § 247d-6d(e)(3).

49. Moreover, Section 247d-6d(e)(10) provides that the **United States Court of Appeals for the D.C. Circuit shall have jurisdiction of an interlocutory appeal by a covered person taken within 30 days of an order denying a motion to dismiss or motion for summary judgment based on an assertion for the immunity from suit**. Critically, unlike the nine sections preceding it, the provisions of section (e) (10) are not limited to claims for "willful misconduct." This provision applies to all motions asserting immunity under the PREP Act. In order for such appeal to occur, the claim must have been removable in the first place.

50. An alternative remedy is also available for any claims barred by 42 U.S.C. § 247d-6d. Under § 247d-6e, an individual is permitted to claim no-fault benefits through the Covered Countermeasure Process Fund for a "covered injury directly caused by the administration or use of a covered countermeasure." In fact, even a claimant alleging "willful misconduct" must first apply for benefits through the Fund under § 247d-6e before bringing an action in the District of Columbia under § 247d-6d(d). *Id*. at § 247d-6e(d)(1). Therefore, it is clear that Congress sought to establish a set of exclusive federal remedies for claims that are preempted under the PREP Act. More simply put, state causes of action for claims relating to covered countermeasures are impermissible as a claimant must either file a claim through the established fund or a Complaint for Willful Misconduct under the PREP Act in the District Court for the District of Columbia. The PREP Act clearly satisfies both prongs of the "complete preemption" analysis thus, preempting state law claims which fall within its scope.

51. OGC Advisory Opinion 21-01, issued on January 8, 2021, which is entitled to *Chevron* deference, also explains that **the PREP Act is a "complete preemption" statute**. The Advisory Opinion states that "[t]he sine qua non of a statute that completely preempts is that it establishes either a federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both." (Exhibit DD to RFJN, pg. 2.) The PREP Act has also been determined to be a complete preemption statute by a state appellate court in New York. *See*

Parker v. St. Lawrence County Public Health Department, 102 A.D.3d 140, 143-45 (N.Y. App.Div. 2012).

52. In a Statement of Interest recently submitted by the Department of Justice in *Bolton v. Gallatin Center for Rehabilitation & Healing, LLC*, Case 3:20-cv-00683, which is pending in the Middle District of Tennessee, the United States also analyzes and then asserts that **the PREP Act is a complete preemption statute with respect to the administration or use of covered countermeasures**. As the U.S. Department of Justice ("DOJ") points out, "**[t]wo key provisions of the PREP Act operate together to demonstrate its completely preemptive nature: the immunity provision and the exclusive alternative remedy provision**." (Exhibit EE to RFJN, pg. 7-10.) The DOJ discussed how the intent of Congress in enacting the prep Act corresponds with a finding of complete preemption:

> An effective response to national health emergencies depends on the prompt and willing cooperation of private partners. Thus, the Act broadly immunizes covered persons from claims relating to their administration of specified countermeasures, while specifying exclusive alternative remedies for certain claims. ***Congress determined that the deterrent and compensatory effects of tort liability, which might be salutary in other contexts, would undermine the nation's ability to protect itself from epidemics and pandemic***s. [Emphasis added]. *Id*. at p. 9.

The Statement of Interest also sets forth that it is the nature of the complaint that determines complete preemption, not the stated claims. (*Id*. at pg. 6.)

53. A number of other statutes with analogous remedial structures have been held to establish complete preemption and original federal jurisdiction:

Labor Management Relations Act ("LMRA"). The Supreme Court has adjudged the LMRA to be a complete preemption statute. Thereunder, any state law claims that are substantially dependent on analysis of a collective-bargaining agreement are preempted by Section 301 of the LMRA and must be brought in federal court. *Caterpillar Inc. v. Williams,* 482 U.S. 386, 393 (1987). However, before an employee may bring a Section 301 claim in court, the employee must "'at least *attempt to exhaust exclusive grievance and arbitration procedures* established by the [collective] bargaining agreement.'"

Campbell v. Kane, Kessler, P.C., 144 F. App'x 127, 130 (2d Cir. 2005) (quotation omitted) [Emphasis added].

Employee Retirement Income Security Act ("ERISA). ERISA, another complete preemption statute, also has a "firmly established federal policy favoring exhaustion of administrative remedies" for purposes of, *inter alia*, reducing the number of frivolous lawsuits, providing a non-adversarial method of claims settlement and minimizing the costs of claims settlement for all. *Kennedy v. Empire Blue Cross & Blue Shield,* 989 F.2d 588, 594 (2d Cir.1993); *Paese v. Hartford Life & Acc. Ins. Co.*, 449 F.3d 435, 445 (2d Cir. 2006).

Air Transportation Safety and System Stability Act ("ATSSSA"). The Second Circuit has also applied the doctrine of complete preemption to the ATSSSA, which is structurally similar to the PREP Act. Congress passed the ATSSSA after the September 11th terrorist attacks to create an exclusive federal cause of action for damages "arising out of the hijacking and subsequent crashes" of the aircraft used in the attacks. ATSSSA § 408(b)(1), 49 U.S.C. §40101. Like the PREP Act, the ATSSA also includes a victim's compensation fund, where a claim is filed with an appointed "Special Master", who reviews the claim to determine whether the claimant is an eligible individual under the Act. ATSSSA § 405, 49 U.S.C. §40101. Claims are limited under the fund and do not include punitive damages awards. Similar to the PREP Act, Congress' principal goals in enacting the ATSSSA "were to provide relief *without litigation* to individuals harmed as a result of the crashes and to *limit the liability of entities* that were likely to be sued for injuries suffered in connection with the crashes." *In re WTC Disaster Site*, 414 F.3d 352, 377 (2d Cir. 2005) (emphasis added). [3]

Federal Tort Claims Act ("FTCA"). The FTCA, which is strikingly similar to the PREP Act, immunizes certain persons from liability and also provides an administrative/judicial remedial scheme for claims falling thereunder. The FTCA affords liability protection to federal employees for any negligent or wrongful acts committed while acting within the scope of their employment, and provides an

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[3] Notably, the PREP Act shares operative language with the ATSSSA. *Compare In re WTC Disaster Site*, 414 F.3d at 375-76 [discussing the breadth and meaning of the operative phrases "arising out of" "resulting from" and "relating to"] *with* 42 U.S.C. § 247d-6d(a)(1).

exclusive federal cause of action in the federal district courts against the United States under specified circumstances. Like the PREP Act, before a judicial action may be instituted, the claimant must first present the claim before the appropriate federal agency for adjudication. 28 U.S.C. § 2675. This jurisdictional requirement cannot be waived, *Celestine v. Mount Vernon Neighborhood Health Ctr.*, 403 F.3d 76, 82 (2d Cir. 2005), resulting in the dismissal of claims where a claimant fails to exhaust the administrative remedies. *See, e.g., Leytman v. United States*, No. 19-3929, 2020 WL 6297440, at *2 (2d Cir. Oct. 28, 2020) [affirming dismissal of pending and unexhausted claims under FTCA for lack of subject matter jurisdiction]. Indeed, the federal remedy under the FTCA, similar to the PREP Act, ensures that "decisions and conduct of federal public servants in the course of their work *will not be adversely affected by fear of personal liability* for money damages and of the burden of defending damage liability claims." *Melo v. Hafer*, 13 F.3d 736, 744 (3d Cir. 1994) (emphasis added).

Like the statutes discussed above, the PREP Act creates an exclusive federal remedy for claims falling thereunder, involving both an administrative and judicial component. 42 U.S.C. § 247d-6e; § 247d-6d(d)(e). This remedial structure was purposefully established by Congress to provide timely and uniform compensation in place of expensive and uncertain litigation, and is explicitly "exclusive of any other civil action or proceeding for any claim or suit *[the PREP Act] encompasses* …." 42 U.S.C. § 247d-6e(d) (emphasis added).

54. Here, both prongs of the "complete preemption" analysis are satisfied by the PREP Act: (1) Congress clearly intended to preempt state law with respect to claims that invoke PREP Act immunity; and (2) Congress clearly intended to create an exclusive federal remedy for such preempted claims. As set forth above, the Fifth Amendment to Secretary Azar's Declaration reiterates that "[t]he plain language of the Prep Act makes clear that there is ***complete preemption of state law***…." 86 Fed. Reg. 7,872, 7,874 (Feb. 2, 2021). The PREP Act meets the requirements for removal jurisdiction as set forth by the U.S. Supreme Court in *Beneficial National Bank v. Anderson*, *supra*, and any claim falling within its broad preemptive ambit is subject to removal under the doctrine of "complete preemption."

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D. The PREP Act Applies Because Defendant Redwood Springs Healthcare Center is a Covered Person

55. Immunity under the PREP Act is afforded to "covered persons" which include a person or entity that is a "program planner" of a covered countermeasure, and/or a qualified person who prescribed, administered, or dispensed such countermeasure. Under the Act, "person" includes "an individual, partnership, corporation, association, entity, or public or private corporation." 42 U.S.C. § 247d-6d (i)(2) and (5). The term "program planner" includes persons/entities "who supervised or administered a program with respect to the administration, dispensing, . . . provision, or use of a . . . qualified pandemic product or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a [HHS Secretary's] declaration . . . ." 42 U.S.C. § 247d-6d (i)(6).

56. A private sector employer or other person can be a "program planner" when it carries out prescribed activities. 85 Fed. Reg. 15,198, 15,199 (Mar. 17, 2020); (See Exhibit B to RFJN). The OGC also issued a letter which provides that a "senior living community" meets the definition of a "program planner" to the extent that it supervises or administers a program with respect to the administration, dispensing, distribution, provision or use of a qualified pandemic or epidemic product, including the provision to a facility to administer or use a covered countermeasure. (Aug. 14, 2020 Letter from HHS Office of General Counsel to Thomas Barker of Foley Hoag, LLP, attached as Exhibit F to RFJN.) The broad definition of "program planner" was also addressed in Advisory Opinion 20-04, issued October 22, 2020, by the OGC. (See Exhibit G to RFJN.)

57. Defendant Redwood Springs qualifies as a "covered person" under the PREP Act. At the time of the allegations set forth in the Complaint, Redwood Springs was acting as a "program planner" and "qualified person." Redwood Springs is a skilled nursing facility licensed by the California Department of Public Health, which employs licensed nursing personnel, including Registered Nurses and Licensed Vocational Nurses, who are authorized to prescribe, administer, or dispense the covered countermeasures set forth in Plaintiff's Complaint (i.e., PPE including facemasks, gloves, gowns, face shields, N95 masks, and COVID-19 testing) under the laws of the State of California. Additionally,

Redwood Springs is a program planner that was supervising and administering an infection control program with respect to the administration, dispensing, provision and use of qualified pandemic and epidemic products.

E. The PREP Act Applies to the Allegations in the Complaint

58. The PREP Act is applicable with respect to a "covered countermeasure," which definition includes:

> (1) a qualified pandemic or epidemic product (as defined in § 247d-6d (i) (7)) . . . or (4) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health ("NIOSH") and that the Health and Human Service Secretary determines to be a priority for use during a public health emergency declared under section 247d. 42 U.S.C. § 247d-6d (i)(1).

A "qualified pandemic or epidemic product" is defined as: a drug, biologic product or device that is:

> (A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured—
> (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or
> (II) to limit the harm such pandemic or epidemic might otherwise cause;
> (ii) a product, manufacture, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious of life-threatening disease or condition caused by a product described in clause (i); or
> (iii) a product or technology intended to enhance the use or effect of a drug, biologic product, or device described in clause (i) or (ii); and
> (B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 262 of this title;
> (ii) the object of research for possible use as described in subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act; or
> (iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug and Cosmetic Act.
> 42 U.S.C. § 247d-6d (i)(7).

59. The OGC issued an omnibus Advisory Opinion on May 19, 2020 to address questions and concerns regarding the scope of the PREP Act immunity for the COVID-19 pandemic. The Opinion summarized the requirements to meet the definition of a qualified pandemic or epidemic product noting that the product:

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(1) must be used for COVID-19; and
(2) must be
(a) approved, licensed, or cleared by FDA;
(b) authorized under an EUA [emergency use authorization];
(c) described in an EUI [emergency use instructions]; or
(d) used under either an Investigational new Drug (IND) application or an Investigational Device Exemption.
(Advisory Opinion 20-01, attached as Exhibit H to RFJN, pg. 4.)

60. Moreover, attached as Appendix A to this Advisory Opinion is a list of the "covered countermeasures" for which emergency use authorizations have been issued by the United States Food and Drug Administration. (See Exhibit I to RFJN.) The list includes twelve pages of COVID-19 test kits, and provides that face shields, gowns, shoe covers, non-surgical isolation gowns, surgical caps, properly labeled non-surgical masks, and certain non-NIOSH approved respirators (N95 masks) are covered by an EUA. Surgical masks are not listed; however, such masks are Class II medical devices which are cleared by the FDA for use. See 21 C.F.R. § 878.4040. Thus, COVID-19 testing kits, face masks, gowns, gloves and other PPE are "qualified pandemic or epidemic products" and "covered countermeasures" under the PREP Act, as such products are either FDA cleared/approved or are included in an EUA.

61. Immunity under the PREP Act "applies to **any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the** . . . distribution . . . **purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure**." 42 U.S.C. § 247d-6d (a)(2)(B) (emphasis added).

62. Plaintiff alleges that Defendant failed to prevent the decedent, Gennie Price, from contracting COVID-19. Such a claim, by its nature, arises out of Redwood Springs' use, distribution, procurement and administration of covered countermeasures/qualified pandemic products (including COVID-19 testing kits, NIOSH approved respiratory protective devices, face masks, and other PPE) used to diagnose, mitigate, prevent, treat or cure the COVID-19 virus, or to limit the harm COVID-19 might otherwise cause thereby triggering application of the PREP Act.

63. In his initial March 10, 2020 Declaration, the HHS Secretary notes that the "PREP Act does not explicitly define the term 'administration' but does assign the Secretary the responsibility to

provide relevant conditions in the Declaration." 85 Fed. Reg. 15,198, 15,200 (Mar. 17, 2020); (Exhibit B to RFJN). In Section IX of the Declaration, the Secretary defines "administration of a covered countermeasure" as the "physical provision of the countermeasures to recipients ***or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients***; ***management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.***" 85 Fed. Reg. at 15,202; (Exhibit B to RFJN (emphasis added)).

64. Under the PREP Act, the Secretary may specify that liability protections are in effect only for Covered Countermeasures obtained through a particular means of distribution. Section VII of the Secretary's initial March 10, 2020 Declaration provides that"

> "liability immunity is afforded to Covered Persons only for Recommended Activities that are related to (a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements; or (b) Activities authorized in accordance with public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency." 85 Fed. Reg. at 15,200; (Exhibit B to RFJN).

65. Moreover, the Fourth Amendment to the Secretary's Declaration Section VII of the Declaration. This Fourth Amendment provides that,

> ***COVID-19 is an unprecedented global challenge that requires a whole-of-nation response that utilizes federal-, state-, and local-distribution channels as well as private-distribution channels. Given the broad scale of this pandemic, the Secretary amends [Section VII of] the Declaration to extend PREP Act coverage to additional private-distribution channels***…. 85 Fed. Reg. at 79,194; (Exhibit E to RFJN, pg. 12 (emphasis added)).

66. The Fourth Amended Declaration specifically provides that Section VII of the Declaration extends liability protection under the PREP Act to Covered Persons for Recommended Activities that are related to "Covered Countermeasures" that are:

> i. Licensed, approved, cleared or authorized by the FDA (or that are permitted to be used under an Investigational New Drug Application or an Investigational Device Exemption) under the FD&C Act or PHS Act to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom; or
> ii. A respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be priority for use during a public

> health emergency declared under section 319 of the PHS Act to prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom. 85 Fed. Reg at 79,194; (Exhibit E to RFJN).

67. The PREP Act was designed to apply to individuals and entities responding to public health emergencies and provides immunity for claims involving "covered countermeasures" under the Act. Plaintiff's claims involve activities and decisions directly related to the delivery, distribution and dispensing of countermeasures to recipients and the management and operation of Redwood Springs' covered countermeasures program, including decisions as to how best to optimize supplies of PPE and utilize COVID-19 testing kits in light of known regional and national shortages. The broad definition of "administration of a covered countermeasure" set forth in the Secretary's Declaration encompasses Redwood Springs' plans and decisions with respect to how best to utilize and optimize supplies of PPE and COVID-19 testing kits, and whether and when the use of such countermeasures is appropriate. Moreover, during the relevant time frame to Plaintiff's claims, Redwood Springs was subject to guidance/directives issued by the Centers for Disease Control and Prevention ("CDC"), Centers for Medicaid and Medicare Services ("CMS"), and the California Department of Public Health ("CDPH"), and was following this applicable public health guidance with respect to the use of PPE and COVID-19 testing. Redwood Springs has thus established that Plaintiff's claims fall within the purview of the PREP Act.

68. Moreover, ***"[p]rioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive, can fall within the PREP Act and this Declaration's liability protections.***" [Emphasis added.] (Exhibit E to RFJN; 85 Fed. Reg 79190, 79194, and 79197.) For example, the PREP Act would be triggered in cases where a plaintiff alleges a failure to use PPE, if the failure was the outcome of some form of decision-making process. (See Exhibit DD to RFJN, pg. 3.) In the January 8, 2021 AO, the OGC further states that "[p]rogram planning inherently involves the allocation of resources and when those resources are scarce, some individuals are going to be denied access to them. Therefore, decision-making that leads to the non-use of covered countermeasures by certain individuals is the grist of program planning, and is expressly covered by the PREP Act." (Exhibit DD to RFJN, pg. 4.)

69. During the time frame relevant to Plaintiff's Complaint there was scarcity of PPE and

COVID-19 testing kits and resources. (See Exhibits U, Y, and FF to RFJN; 85 Fed. 17592 – Notice of Designation of Scarce Material, and https://www.bloomberg.com/news/articles/2020-04-07/coronavirus-testing-accuracy-and-availability-shortages-remain.) Further, as established above, Redwood Springs was a "program planner" since it supervised and administered its infection control program and protocols which included decisions pertaining to the allocation and administration of covered countermeasures such as PPE, testing, etc., including how best to optimize supplies and when use is appropriate. Redwood Springs' actions with respect to the coordination and implementation of its infection control program thus, inherently involve the prioritization and purposeful allocation of covered countermeasures, including COVID-19 testing and PPE.

70. This case does not involve nonfeasance or total inaction but instead relates to propriety of the measures implemented by Redwood Springs, including those pertaining to PPE and COVID-19 testing. Redwood Springs has thus established that PREP Act applies to Plaintiff's claims thereby providing Defendant with immunity under the Act.

V. THIS CASE RAISES SUBSTANTIAL AND IMPORTANT FEDERAL ISSUES THUS PROVIDING EMBEDDED FEDERAL QUESTION JURISDICTION OVER PLAINTIFF'S CLAIMS

71. Federal jurisdiction is further appropriate as this state action "arises under" federal law and raises a substantial federal issue. *See Grable & Sons Metal Products v. Darue Eng'g. & Mfg.*, 545 U.S. 308 (2005). The applicability of the PREP Act poses a substantial federal issue which would serve to clarify and determine vital issues of federal law. Federal question jurisdiction over state law claims may be sustained if the claims present a substantial, embedded question of federal law. *Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804, 808 (1986). In *Grable & Sons Metal Products v. Darue Eng'g. & Mfg.*, 545 U.S. 308 (2005), the United States Supreme Court held that removal is appropriate if (1) the state law claim necessarily raises a disputed and substantial issue; and (2) a federal court may entertain the claims without disturbing federal/state comity principles. *Id*. at 314.

72. In his Fourth Amended Declaration, Secretary Azar makes explicit that the PREP Act presents substantial federal legal and policy issues, and that there are substantial federal legal and policy

interests within the meaning of *Grable*, in having a unified whole-of-nation response to the COVID-19 pandemic among federal, state, local and private-sector entities. The Secretary attests that,

> [t]he world is facing an unprecedented global pandemic. To effectively respond, there must be a more consistent pathway for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world. **Thus, there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products v. Darue Engineering & Mfg*, 545 U.S. 308 (2005), in having a uniform interpretation of the PREP Act.** Under the PREP Act, the sole exception to the immunity for suit and liability of covered persons is an exclusive Federal cause of action against a Covered Person for death or serious physical injury proximately caused by willful misconduct of such Covered Person. In all other cases, an injured party's exclusive remedy is an administrative remedy under section 319F-4 of the PHS Act. Through the PREP Act, Congress delegated to me the authority to strike the appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act declarations. 85 Fed. Reg. at 79,194; (Exhibit E to RFJN, pgs. 13-14, 25-26) (emphasis added).

73. Thus, by the analysis provided by and the express terms of the Secretary's Fourth Amended Declaration, removal is proper under *Grable* because Plaintiff's state law claims raise a substantial issue of federal law involving the interpretation and application of the PREP Act. Secretary Azar's Fourth Amended Declaration directly addresses the federal interest in cases such as this, by stating not once, but twice: "**there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mfg.*, 545 U.S. 308 (2005)**." 85 Fed. Reg. at 79,194; (Exhibit E to RFJN). Here, Plaintiff alleges that Defendant failed to prevent the decedent, Gennie Price, from contracting COVID-19. Such a claim, by its nature, arises out of Redwood Springs' administration of covered countermeasures and invokes the PREP Act. Thus, the federal legal and policy issues described in Secretary Azar's Fourth Amended Declaration control and require this Court to retain this action.

74. This case involves issues of national importance. While Plaintiff does allege state causes of action, Plaintiff's claims relate to Defendant's response to a national public health state of emergency, which has not been seen by this Country in over a century. The healthcare response to this pandemic was coordinated at a national level by HHS, the CDC, the FDA and CMS, and entailed the issuance of detailed directives to healthcare providers to identify and sequester infected patients, which patients under investigation were to be tested, and the use of PPE. All positive cases of COVID-19

were reported to the CDC, and initially all testing was conducted solely through the CDC. Plaintiff's Complaint raises issues with respect to Defendant's response to a national pandemic and the response to the pandemic coordinated at a federal level; as well as the procurement, use, allocation, distribution and administration of PPE and COVID-19 testing, which invoke a substantial federal question regarding the extent to which the broad immunities afforded under the PREP Act apply to the conduct of Defendant.

75. The application of the PREP Act raises a substantial federal issue which is disputed. The allegations in the Complaint arise out of Defendant's response to the COVID-19 pandemic and are inextricably intertwined with and invoke the PREP Act and the Declaration of the HHS Secretary. This Federal Court has a substantial interest in determining the application of the PREP Act in this matter. The PREP Act and its triggering immunity has been invoked in exceptionally rare circumstances since it was enacted in 2005. The PREP Act and the HHS Secretary's Declaration confer a broad and sweeping immunity to individuals and entities fighting the COVID-19 pandemic during this declared state of emergency. The unique character of the COVID-19 virus, as well as its high communicability, required the Secretary to set forth an expansive Declaration covering broad categories of measures to fight the pandemic including COVID-19 testing and PPE, all of which require interpretation as to the scope and application. Thus, there can be no doubt that there is a substantial and compelling interest for the PREP Act and the Secretary's Declaration to be interpreted by the federal courts. Moreover, the federal courts are uniquely and properly positioned to interpret Congressional intent and interests of the federal government.

76. This case also satisfies the second prong set forth in *Grable*. Federal jurisdiction over Plaintiff's claims will not disturb federal-state comity principles under *Grable*. As set forth by the Secretary in his Fourth Amended Declaration: "Through the PREP Act, Congress delegated to me the authority to strike the appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act declaration." 85 Fed. Reg at 79,194; (Exhibit E to RFJN). Moreover, the plain, statutory language of the PREP Act expresses a strong federal interest and a clear intention to supersede or preempt state control of the issues raised by Plaintiff's Complaint.

77. Congress did not intend the application of PREP Act immunity to be decided by state courts. As such, this Court would not be disturbing or infringing on any balance of state and Federal

judicial responsibilities by retaining jurisdiction. To the contrary, the plain language of the statute seeks to assert broad federal authority over the issues arising under the Act, and seeks to eliminate all semblance of state court control. The Secretary's Fourth Amended Declaration makes explicitly clear that there is exclusive federal jurisdiction over lawsuits involving covered countermeasures, and that this federal jurisdiction is essential to the uniform provision of a national response to the COVID-19 pandemic and the PREP Act. See 85 Fed. Reg. 79,190; (Exhibit E to RFJN).

VI. REMOVAL IS PROPER BECAUSE THIS COURT HAS JURISDICTION UNDER THE FEDERAL OFFICER STATUTE

78. Removal is proper under 28 U.S.C. §1442(a)(1), which provides for removal when a defendant is sued for acts undertaken at the direction of a federal officer. Removal is appropriate under §1442(a)(1), when the removing defendant establishes that:

(a) Defendant is a "person";

(b) Defendant was acting under the direction of a federal officer when it engaged in the allegedly tortious conduct;

(c) There is a causal nexus between the plaintiff's claims and the defendant's actions under federal direction; and

(d) Defendant has raised a colorable defense based upon federal law.

Goncalves v. Rady Children's Hospital San Diego 865 F.3d 1237, 1244 (9th Cir. 2017). Courts have a duty to broadly interpret Section 1442 in favor of removal, which "should not be frustrated by a narrow, grudging interpretation" of the statute. *Ibid.* (quotations and citations omitted).

79. This statute creates removal jurisdiction even as to cases that otherwise could not be commenced in or removed to federal court. *See Jefferson County, Ala. v. Acker*, 527 U.S. 423, 431 (1999) (finding no diversity in a common law negligence action against government driver who lived in same state as plaintiff); *see also Mir v. Fosburg* 646 F.2d 342, 344 (9th Cir. 1980). Moreover, unlike the usual rule that removability in federal question cases must appear on the face of a well-pleaded complaint, cases may be removable under Section 1442(a) when a federal officer or agency raises a "colorable federal defense". See *Jefferson County, Ala. v. Acker*, *supra*, 527 U.S. at 431.

80. Here, Defendant is a member of the nation's critical infrastructure and satisfies all elements for removal under Section 1442(a)(1). Defendant is a "person" for the purpose of the federal officer statute. The term "person" includes "corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals." 1 U.S.C. § 1; *see also Goncalves*, *supra*, 865 F.3d at 1244.

81. As part of the nation's critical infrastructure, Defendant was also acting under the direction of a federal officer when it engaged in the alleged tortious conduct. The U.S. Supreme Court has held that the phrase "acting under" involves "an effort to *assist*, or help *carry out*, the duties or tasks of the federal superior." *Watson v. Philip Morris Cos*., 551 U.S. 142, 152 (2007); *see also In re Commonwealth's Motion to Appoint Counsel Against or Directed to Defender Association of Philadelphia*, 790 F.3d 457 (3d Cir. 2015). The "acting under" requirement is broad and is to be liberally construed. *Watson*, *supra*, 551 U.S. at 147.

82. "[R]emoval by a 'person acting under' a federal officer must be predicated upon a showing that the acts that form the basis for the state civil or criminal suit were performed pursuant to an officer's direct orders or to comprehensive and detailed regulations. *Cf. Bakalis v. Crossland Savings Bank,* 781 F.Supp. 140, 144-145 (E.D.N.Y. 1991) (finding 'The rule that appears to emerge from the case law is one of 'regulation plus...'); *Ryan v. Dow Chemical Co.*, 781 F. Supp. 934, 947 (E.D.N.Y. 1992) (finding that the "control requirement can be satisfied by strong government intervention and the threat that a defendant will be sued in state court 'based upon actions taken pursuant to federal direction.'"); *see Fung v. Abex, Corp*., 816 F. Supp. 569, 572 (N.D. Cal. 1992). The "acting under" requirement is met when the defendant is acting pursuant to detailed and ongoing instructions from a federal officer. *Winters v. Diamond Shamrock Chem. Co.*, 149 F.3d. 387 (5th Cir. 1998).

83. Defendant meets the "acting under" prong for removal based on the federal officer statute. Here, Plaintiff contends that the acts and omissions of Defendant, with respect to their response to the COVID-19 pandemic, caused the decedent, Gennie Price, to contract the virus which led to his death. Specifically, Plaintiff alleges that Defendant failed to prevent the decedent from contracting COVID-19. (See Exhibit A to RFJN, Complaint ¶¶ 1, 9, 14, 30, 34, 47, 48, 50, 52.)

84. Prior to the current national pandemic, regulation of nursing homes was very general in nature. In 1987, Congress enacted legislation, known as the Nursing Home Reform Act, requiring nursing homes participating in Medicare and Medicaid to comply with certain quality of care rules and regulations. See 42 U.S.C. § 1396r, 42 U.S.C. § 1395i-3 and 42 C.F.R. § 483.1 through 42 C.F.R. § 483.95. CMS, contracts with state surveyors, including the California Department of Public Health in California ("CDPH"), to perform federal surveys to ensure that facilities accepting Medicare and Medicaid (Medi-Cal) payments comply with federal laws and regulatory requirements. Generally, and prior to the pandemic, these surveyors conducted site visits to evaluate whether facilities are in compliance with federal requirements and regulations[4]. See 42 U.S.C. § 1395aa; and 42 CFR § 488.10. If CDPH surveyors found a "deficiency" in a facility's compliance with federal regulations, CDPH would issue a deficiency or citation, and on occasion use the CMS enforcement remedy of a "directed plan of correction," under which the facility would develop and submit a plan of correction, which would then be enforced on behalf of CMS by CDPH.

85. In January, 2020, in response to the pandemic and the national state of emergency, CMS and the CDC began issuing detailed directives to healthcare facilities as members of the nation's critical infrastructure and as part of the coordinated national effort to respond to and contain the COVID-19 pandemic. CDPH surveyors, contracted by CMS, were supervising skilled nursing facilities with respect to all aspects of infection control and the pandemic response and ensuring strict compliance with the CMS directives. The issuance of timely and evolving guidance in response to a public health emergency was in contrast to the role of CMS before the pandemic. Prior to the pandemic, the focus was on ensuring compliance with existing regulations. However, throughout the pandemic, CMS and CDPH as its agent, specifically instructed facilities to take or not take particular clinical and operational actions in the absence of finding deficiencies that would otherwise require the facility to develop its own plan of correction. These directives included the following:

[4] CDPH contracts with Los Angeles County to provide federal survey and certification services in the county. The CDPH/ Los Angeles County surveyors are hereafter referred to as CDPH surveyors. See https://data.chhs.ca.gov/dataset/licensingand-certification-district-offices-california,

A. Early directives to skilled nursing facilities focused on monitoring residents and staff for symptoms and protecting healthcare providers from infection due to contact with symptomatic patients. Facilities were advised to adhere to standards for infection prevention and take steps to prepare for COVID-19.

B. In January and February, 2020, the CDC issued a number of health updates regarding the 2019 Coronavirus, as well as criteria to guide the evaluation and testing of patients under investigation ("PUI") for COVID-19. Healthcare providers were advised to identify PUI based on clinical features (i.e., fever or signs/symptoms of lower respiratory illness), travel to an affected geographic region and contact with a laboratory confirmed COVID-19 patient. Persons meeting the PUI criteria were to be tested and healthcare providers were advised to immediately notify their local or state health department in the event they were evaluating a PUI. State health departments in turn were instructed to immediately contact the CDC and complete a PUI case investigation form. Initially COVID-19 testing was conducted solely through the CDC, which assisted local/state health departments in the collection, storage and shipment of specimens to the CDC. During this time, the CDC also directed healthcare providers to use standard, contact and airborne precautions when interacting with PUI. (See January 8, 2020, CDC Health Update Outbreak of Pneumonia of Unknown Etiology (PUE) in Wuhan China, attached as Exhibit J to the RFJN; January 17, 2020 CDC Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus (2019-n-coV) in a Healthcare Setting, attached as Exhibit K to the RFJN; January 24, 2020 CDC Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus (2019-n-coV) in a Healthcare Setting, attached as Exhibit L to the RFJN.)

C. On February 1, 2020, the CDC issued an "Update and Interim Guidance on the Outbreak of 2019 Novel Coronavirus" to provide further guidance to healthcare providers regarding 2019-nCoV 2019 (the 2019 Novel Coronavirus, now known as COVID-19). ***The guidance was part of the "ongoing US public health response . . . to identify and contain [the] outbreak and prevent sustained spread of 2019-nCoV in the United States"*** and addressed infection prevention and control specific to 2019-nCoV. (See February 1, 2020 CDC Health Update and Interim Guidance on the

Outbreak of 2019 Novel Coronavirus (2019-n-coV), attached as Exhibit M to the RFJN (emphasis added).) In the update, the CDC noted that the first United States case was identified on January 21, 2020, and had recently traveled from Wuhan, China. Since that time, six additional cases had been confirmed in the U.S., four among persons who had traveled from Wuhan and one a close contact of a confirmed case. This document further provided updated directives related to screening of patients in healthcare facilities, and coordination with local health departments for testing and reporting of results. In the update, the CDC set forth the criteria for assessing patients for COVID-19, and advised that patients who meet the criteria should be asked to wear a surgical mask as soon as they are identified and evaluated in a private room with the door closed, ideally an airborne infection isolation room if available. Healthcare personnel entering the room were again directed to use standard precautions, contact precautions, airborne precautions and eye protection. Persons with a confirmed or suspected COVID-19 infection who were hospitalized were to be evaluated and cared for in a private room with the door closed, ideally an airborne infection isolation room. (See Exhibit M to RFJN.)

D. In January and February, the California Department of Public Health ("CDPH") issued a number of All Facilities Letters (AFLs) pushing out the information and directives issued by the CDC with respect to identification of PUI and infection prevention and control. (See AFL 20-09, 20-10, 20-11, 20-13, and 20-15, attached collectively as Exhibit N to the RFJN.)

E. On February 6, 2020, CMS took direct action to prepare healthcare facilities for the national response to the emerging 2019 Novel Coronavirus by issuing a Memorandum to State Survey Agency Directors (i.e., CDPH). The memo directed healthcare providers to adhere to CDC directives regarding the use of standard, contact and airborne precautions when interacting with PUI and advised facilities to have PPE measures and protocols in place. (See February 6, 2020 CMS Memorandum QSO 20-09-ALL, attached as Exhibit O to the RFJN.)

F. On February 28, 2020, the CDC issued a Health Update and Interim Guidance on the Outbreak of 2019 Novel Coronavirus (COVID-19) for healthcare providers. The Update noted that to date there had been limited spread in the United States. As of February 26, 2020, there were a total of 61 cases in the country, 46 of whom were repatriated persons from high-risk settings. One patient, with no travel history or links to other known cases was reported on February 26, 2020 in California. The

guidance again included criteria to guide the evaluation and testing of patients under investigation ("PUI") for COVID-19. Healthcare providers were advised to identify PUI based on clinical features (i.e., fever or signs/symptoms of lower respiratory illness), travel to an affected geographic region and contact with a laboratory confirmed COVID-19 patient. Persons meeting the PUI criteria were to be tested. This update further added patients with fever and signs/symptoms of lower respiratory illness without an alternative explanatory diagnosis and no identified source of exposure to the list of those who should be tested. At this time, testing was being performed at state public health laboratories and the CDC. (See February 28, 2020 CDC Health Update and Interim Guidance on Outbreak of Coronavirus Disease 2019 (COVID-19) attached as Exhibit P to the RFJN.)

G. On or about March 3, 2020, the CDC issued "Strategies to Prevent the Spread of COVID-19 in Long-Term Care Facilities (LTCF)". (Exhibit Q to RFJN.) This publication, issued specifically to long term care facilities such as Redwood Springs, reiterated that standard, contact and droplet precautions with eye protection were to be used in the care of residents with an undiagnosed respiratory infection. Facilities were instructed to make PPE, including facemasks, eye protection, gowns and gloves available immediately outside the resident's room and to post signs on the door or wall outside the room of the residence to clearly describe the type of precautions needed and the required PPE. (See Exhibit Q to RFJN.)

H. On March 3, 2020, the CDPH pushed the information contained in the CDC February 28, 2020 Interim Guidance and the CDC's March 3, 2020 guidance to long term care facilities in AFL 20-17. (See Exhibit R to RFJN.)

I. On March 4, 2020, CMS issued a Memorandum to State Survey Agency Directors regarding Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in nursing homes. The State Survey Agency, as agent for CMS, was also responsible for disseminating the contents of the QSO memo to the States' nursing homes. The Memo instructed facilities to screen visitors for international travel, symptoms of respiratory infection, and contact with someone with or under investigation for COVID-19, and to restrict entry of visitors who meet these criteria. Facilities were advised to screen staff for the criteria as well, and that staff who meet the criteria should not report to work. The CMS also included directions as to when to transfer a resident with a suspected or

confirmed COVID-19 infection to a hospital, and under what conditions a nursing home may accept patients diagnosed with COVID-19. CMS advised facilities to follow the available CDC guidance regarding infection prevention and control. (See CMS Memo QSO 20-14-NH, attached as Exhibit S to RFJN.)

J. On March 8, 2020, the CDC issued further Updated Guidance on Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19). (See Exhibit T to RFJN.) The CDC advised that with the expanding spread of COVID-19, additional areas of geographic risk were being identified and the criteria for considering testing were being updated to reflect this spread. The Update indicated that additional COVID-19 testing was becoming available in clinical laboratories pursuant to FDA Emergency Use Authorizations. With increased access to testing, the criteria for testing had been expanded to include more symptomatic persons, such as older adults (age 65 and older). Thus, as part of the coordinated national effort to control and mitigate the spread of the pandemic, the CDC had been specifically directing which persons could be tested. The March 8, 2020 update additionally provided detailed instructions for the collecting of specimens. (See Exhibit T to RFJN.)

K. On March 10, 2020, the CDC issued Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings. (See Exhibit U to RFJN.) The publication again reiterated the directive regarding use of standard and transmission-based precautions, and directed healthcare providers who enter the room of a patient with known or suspected COVID-19 to adhere to standard precautions and use a respirator or facemask, gown, gloves and eye protection. The CDC instructed that patients with known or suspected COVID-19 should be cared for in a single-person room with the door closed. Airborne infection isolation rooms were to be reserved for patients undergoing aerosol generating procedures. The March 10, 2020 CDC publication further noted that "[m]ajor distributors in the United States have reported shortages of PPE, specifically N95 respirators, facemask and gowns." (Exhibit U to RFJN.) Based on a local and regional situational analysis of PPE supplies, the CDC directed that facemasks were an acceptable alternative when the supply chain of respirators cannot meet the demand. During this time, respirators were to be prioritized for situations where respiratory protection is most important. Healthcare providers were advised that available respirators should be prioritized for procedures that are

likely to generate respiratory aerosols, which pose the highest exposure risk to healthcare providers. In the publication, the CDC further advised that in the event of a shortage of medical gowns, gowns should also be prioritized for aerosol generating procedures.

L. On March 10, 2020, CMS issued a Memorandum providing an update regarding the PPE instructions issued by the CDC on March 10. (See CMS Memo QSO 20-17-ALL, attached as Exhibit V to RFJN.)

M. On March 11, 2020, CDPH issued an All Facilities Letter (AFL) notifying long-term care facilities of the latest CDC and CMS directives for infection control and prevention and the March 4, 2020 visitation restrictions issued by CMS. (See CDPH AFL 20-22, attached as Exhibit W to RFJN.) Redwood Springs followed these directives and the directives issued prior to this, in an effort to assist and help carry out the CDC and CMS' goal of containing and responding to the pandemic.

N. On March 13, 2020, President Trump declared the COVID-19 outbreak a national emergency. Following this proclamation, the CDC and CMS took swift action to waive restrictions and expand capacity for healthcare providers and suppliers to coordinate the national response to the nationally declared state of emergency. On March 13, 2020, CMS issued revised infection control and prevention directives for nursing homes to prevent the transmission of COVID-19. In the Memo, facilities were ordered to restrict visitation of all visitors and non-essential health care personnel, cancel communal dining and all group activities, implement active screening of residents and staff for fever and respiratory symptoms, and screen all staff at the beginning of their shift for fever and respiratory symptoms. Additional direction was provided regarding patient transfers and acceptance of patients with COVID-19. Facilities were ordered to continue to follow applicable CDC guidelines. (See CMS Memo QSO 20-14-NH, attached as Exhibit X to RFJN.)

O. On March 17, 2020, the CDC issued documents containing instructions to optimize the supply of eye protection, isolation gowns, N95 respirators and face masks. The documents provided a series of specific directives relating to the use of PPE based on whether the facility was in conventional capacity (normal operation), contingency capacity (experiencing temporary expected PPE shortages), or crisis capacity (involving periods of known PPE shortages necessitating strategies that are no commensurate with standard U.S. standards of care). For facilities in contingency capacity, the CDC

directed that extended use of facemasks should be implemented and that the use of facemasks should be restricted for use by healthcare providers rather than patients for source control. During crisis capacity, facilities were to prioritize facemask use during activities where prolonged face-to face or close contact with a potentially infectious patient is unavoidable, exclude healthcare providers at higher risk for severe illness from COVID-19 from contact with known or suspected COVID-19 patients, use a face shield with no mask, and in settings where facemasks were not available, use homemade masks. In the document pertaining to optimizing the use of N95 respirators, the CDC instructed that (1) if the healthcare provider was to remain six feet away from a symptomatic patient, no facemask or N95 respirator was required; (2) if the healthcare provider was to be within three to six feet of a symptomatic patient, a facemask should be used; and (3) if the healthcare provider was to be within three feet of a symptomatic patient including providing direct patient care, an N95 respirator should be used if available. When an N95 respirator was not available, healthcare providers were instructed to wear a surgical mask and exclude healthcare providers at higher risk from severe illness from contact with an infectious patient. (See documents attached collectively as Exhibit Y to RFJN.)

P. On March 20, 2020, CMS issued a memo entitled Prioritization of Survey Activities. In the Memo, CMS advised that CMS surveyors would be conducting targeted infection control surveys of providers identified in collaboration with the CDC and the HHS Assistant Secretary for Preparedness and Response to ensure providers are implementing actions to protect the health and safety of individuals to respond to the COVID-19 pandemic. (See CMS Memo QSO 20-20-ALL, attached as Exhibit Z to RFJN.) A skilled nursing facility would be subject to citation, and fines for failure to implement the directives from CMS. **Thus, the directives from CMS (which followed and instructed facilities to follow the CDC guidance) were mandates**, not recommendations.

Q. On March 21, 2020, the CDC issued further guidance specifically aimed at long term care facilities entitled "Preparing for COVID-19: Long-term Care Facilities Nursing Homes." (See Exhibit AA to RFJN.) In this publication, nursing homes were told to restrict visitation, restrict all volunteers and non-essential healthcare personnel, cancel group activities and communal dining, implement active screening of residents and healthcare providers for fever and respiratory symptoms, and make PPE available in areas where resident care is provided and place a trash can near the exit

inside the resident's room so staff can discard PPE prior to exiting. The CDC further directed that,

> residents with known or suspected COVID-19 do not need to be placed in an airborne infection isolation room (AIIR) but should ideally be placed in a private room with their own bathroom. Room sharing might be necessary if there are multiple residents with known or suspected COVID-19. As roommates of symptomatic residents might already be exposed, it is generally not recommended to separate them in this scenario. (Exhibit AA to RFJN.)

R. On April 2, 2020, CMS issued new guidelines aimed at long-term care facilities to "mitigate the spread" of COVID-19. (See Exhibit BB to RFJN.) In doing so, CMS noted that "[l]ong-term care facilities are a critical component of America's healthcare system." CMS stated that, "CMS and CDC have worked together to swiftly issue unprecedented targeted direction to the long-term care facility industry, including a general prohibition of visitors implemented on March 13, 2020, as well as strict infection control and other screening recommendations." (Exhibit BB to RFJN.) CMS further noted that the CDC and CMS were providing "critical, needed leadership for the Nation's long-term care facilities to prevent further spread of COVID-19" and that long term care facilities were to immediately implement symptom screening for all persons (residents, staff, visitors, outside healthcare workers, vendors, etc.) entering a long-term care facility. Facilities were ordered to specifically ask about COVID-19 symptoms and to check the temperature of all visitors, as well as limit access points and ensure that all accessible entrances have a screening station. Every resident was also to be assessed for symptoms and have their temperature checked every day, and patients and residents entering facilities screened for COVID-19 through testing, if available. CMS ordered facilities to ensure all staff were using appropriate PPE when interacting with residents to the extent PPE was available and per CDC guidance on the conservation of PPE. CMS further directed long term care facility staff to wear a facemask while in the facility for the duration of the state of emergency, to wear full PPE for the care of any resident with known or suspected COVID-19, and if COVID-19 transmission occurs in the facility, healthcare personnel were to wear full PPE in the care of all residents irrespective of COVID-19 diagnosis and symptoms. Further, to avoid transmission within long-term care facilities, the facilities were advised to use separate staffing teams for COVID-19 positive residents to the best of their ability, and to work with state and local leaders to designate separate facilities or units within a facility to separate COVID-19 negative residents from COVID-19 positive residents and individuals with

unknown COVID-19 status. (Exhibit BB to RFJN.)

86. This case involves a full-blown national health emergency and efforts made by the federal government in targeting the nation's healthcare industry—in particular, nursing facilities that are part of the nation's critical infrastructure—to help carry out this important goal, which is distinct from the typical regulator/regulated relationship described in *Watson*. *Cf. Watson,* 551 U.S. 142, 157. Nursing facilities are part of the critical national healthcare infrastructure and were among the first responders to the national COVID-19 pandemic. They manned the front lines of the pandemic during its most critical phases and where the danger to the public and to themselves was most acute. Significant and direct oversight by the federal government was critical in the effort to combat this infectious disease outbreak. Defendant was enlisted to assist the federal government, and hence, "acted under" a federal officer or agency in fighting the COVID-19 scourge, which has been ravaging the nation and the world.

87. In summary, through the federal directives issued by the CDC, CMS, and the CDPH surveyors contracted by CMS, federal authorities were making the operational decisions as it related to the clinical pandemic response in skilled nursing facilities. Facilities were ordered to restrict visitation, cancel communal dining, implement active screening and staff for fever and respiratory symptoms, screen staff at the beginning of their shift for fever and respiratory symptoms and actively take their temperature and document the absence of shortness of breath and any new or change in cough and sore throat. Facilities were instructed on which patients and staff to test for COVID-19, under what circumstances to use and how to conserve PPE, when to permit staff who had COVID-19 to return to work, and how to handle the isolation of residents infected with COVID-19 and those under investigation for COVID-19. These very detailed clinical directives and instructions to these members of the nation's critical infrastructure represented a marked departure from the typical regulatory structure that existed before the pandemic. Moreover, as acknowledged by HHS Secretary Azar in his Fourth Amended Declaration: "COVID-19 is an unprecedented global challenge that requires a whole-of-nation response that utilizes federal-, state- and local-distribution channels as well as private-distribution channels [for the provision of covered countermeasures]." 85 Fed. Reg. at 79,194; (Exhibit E to RFJN, p. 12).

88. At all relevant times, Redwood Springs was acting as part of the nation's critical infrastructure at the specific direction of federal authorities to address the on-going federal effort and national state of emergency to contain the COVID-19 pandemic, and prevent the spread of the virus. All actions taken by Redwood Springs in preparation for and response to the COVID-19 pandemic, were taken "in an effort to assist, or help carry out, the duties or tasks" as ordered by the CDC and CMS, and CDPH surveyors (per the contract with CMS), and performed pursuant to the direct orders and comprehensive and detailed directives issued by these agencies. Redwood Springs was acting at the direction of the federal government to prevent, treat and contain COVID-19 at the facility and in its care and treatment of Gennie Price.

89. Next, to establish removal under the federal officer statute, a defendant must show "a causal nexus between the plaintiff's claims and the defendant's actions under federal direction." *Winters v. Diamond Shamrock Chemical Co*., 149 F.3d 387, 398 (5th Cir. 1998).

90. Here, Plaintiff alleges that due to the wrongful acts and omissions of Defendant, the decedent, Gennie Price, became infected with COVID-19 during her residency at Redwood Springs and died due to the virus on April 22, 2020. (See Exhibit A to RFJN, Complaint ¶¶ 1, 10, 11, 12, 13, 14, 15, 16, 17, 38, 41, 47, 48, 50, 52.) Redwood Springs' response to the COVID-19 pandemic as it relates to the claims of Plaintiff (i.e., the care and treatment of Gennie Price) was directly related to the orders and directives issued by the federal government. There is a clear causal nexus between the claims against Redwood Springs and the actions taken by Redwood Springs at the direction of the federal government including, but not limited to, the direction of CDC, CMS, as well as by representatives of CDPH, the State Survey Agency acting under contract with CMS, with respect to the response to the pandemic at the facility and the administration of care to Gennie Price. The nexus element is met as Redwood Springs was following the orders/directives of CMS with regard to infection control, COVID-19 testing and the use of PPE.

91. Lastly, Defendant meets the final requirement as it intends to assert colorable federal defenses. For purposes of removal, the defense must be "colorable" and need not be "clearly sustainable" as the purpose for the removal statue is to secure the validity of the defense may be tried in federal court. *Willingham v. Morgan*, 395 U.S. 402, 407 (1969). The colorable federal defense element

is met where a defendant alleges its actions were justified as the defendant was complying with federal directives with respect to the alleged wrongful acts. *See Venezia v. Robinson*, 16 F.3d 209, 212 (7th Cir. 1994); and *Mesa v. California*, 489 U.S. 121, 126-127 (1989); *see also Rural Community Workers Alliance v. Smithfield*, No. 5:20-CV-06063-DGK, 2020 WL 2145350 (W.D. Mo. May 5, 2020) (finding that compliance with federal guidelines aimed to protect employees from COVID-19 exposure served as a defense to civil liability). Here, Defendant Redwood Springs was complying with federal directives and regulations issued by CMS, the CDC, and CDPH, the CMS contracted state surveyors, in responding to all aspects of the COVID-19 pandemic.

92. As a colorable defense, Defendant also asserts an immunity defense under the PREP Act as set forth at 42 U.S.C. 247d-6d(a)(1). This Act provides for immunity of "covered persons" from "suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of covered countermeasure" provided there has been a declaration issued by the Secretary of Health and Human Services with respect to such countermeasure. On March 10, 2020, the HHS Secretary issued a Declaration invoking the PREP Act for the COVID-19 pandemic. The Declaration was effective as of February 4, 2020. 85 Fed. Reg. 15,198; (See Exhibit B to RFJN). Redwood Springs is a "covered person" under the Act. 85 Fed. Reg. at 15,199; (See Exhibit B to RFJN).

93. Under the PREP Act and the Secretary's initial Declaration, "covered countermeasures" include any qualified pandemic or epidemic product; and any drug, biologic product or device. A "qualified pandemic or epidemic product" is defined as a drug, biologic product or device, which is a product manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat or cure a pandemic or epidemic; or to limit the harm such pandemic or epidemic might otherwise cause. The Secretary's Declaration also included as covered countermeasures any antiviral drug, any biologic, any diagnostic, any other device or any vaccine used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product. 85 Fed. Reg. at 15,199-15,1200; (See Exhibit B to RFJN).

94. In the initial Declaration, the Secretary declared that "Administration of Covered Countermeasures means physical provision of the countermeasures to recipients, ***or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures***." 85 Fed. Reg. at 15,202 (emphasis added); (Exhibit B to RFJN).

95. The Secretary subsequently issued an Amended Declaration under the PREP Act, which was effective as of March 27, 2020. 85 Fed. Reg. 21,012 (Apr. 15, 2020); (See Exhibit C to RFJN). The Amendment added respiratory protective devices approved by NIOSH (National Institute for Occupational Safety and Health) as a covered countermeasure under the PREP Act. In the Amendment, the Secretary stated that "any respiratory protective devices approved by NIOSH . . . is a priority for use during the public health emergency that [the Secretary] declared on January 31, 2020. . . for the entire United States to aid in response of the nation's health care community to the COVID-19 outbreak." 85 Fed. Reg. at 21,013; (See Exhibit C to RFJN).

96. On June 4, 2020, the Secretary further amended the March 10, 2020 Declaration to clarify that covered countermeasures under the Declaration include qualified products that limit the harm COVID-19 might otherwise cause. This Amendment was effective as of February 4, 2020. 85 Fed. Reg. 35,100 (June 8, 2020); (See Exhibit D to RFJN).

97. Plaintiff's Complaint alleges that Defendant failed to prevent the decedent, Gennie Price, from contracting COVID-19. Such a claim, by its nature, relates to Redwood Springs' administration and/or use of covered countermeasures and qualified pandemic products including facemasks, gloves, gowns, N95 masks, and COVID-19 testing kits, used to diagnose, mitigate, prevent, treat or cure COVID-19 or to limit the harm COVID-19 might otherwise cause, and therefore falls under the PREP Act, which provides Defendant with immunity for such claims. Thus, the claims in Plaintiff's Complaint relate to "covered countermeasures" under the PREP Act, which qualify for and trigger immunity from liability for the claims in this action.

98. Removal to federal court is proper in this case, as Defendant has established that all elements for removal under the federal officer statute have been met.

WHEREFORE, Defendant Spruce Holdings, LLC dba Redwood Springs Healthcare Center, having established that this case is properly removed to Federal Court, provide notice pursuant to 28 U.S.C. § 1446, that the action pending in the Superior Court of the State of California County of Tulare, Case No. VCU286614, is properly removed to the United States District Court for the Eastern District of California, and respectfully request that this Court exercise jurisdiction over this case.

Dated: June 1, 2021

WILSON GETTY LLP

By: /s/ Evan J. Topol
William C. Wilson
Kim S. Cruz
Ryan G. Canavan
Evan J. Topol

Attorneys for Defendant SPRUCE HOLDINGS, LLC dba REDWOOD SPRINGS HEALTHCARE CENTER (erroneously sued and served as REDWOOD SPRINGS HEALTHCARE CENTER and SPRUCE HOLDINGS, LLC)

Marx Ford, individually and as SII to the Estate of Gennie Price, et al. v. Redwood Springs Healthcare Center, et al.
United States District Court, Eastern District of California
Case No.
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PROOF OF SERVICE

I am employed in San Diego County. I am over the age of 18 and not a party to this action. My business address is 12555 High Bluff Drive, Suite 270, San Diego, California 92130.

On **June 1, 2021**, I served the foregoing documents, described in this action as:

- **DEFENDANT'S NOTICE OF REMOVAL OF ACTION UNDER 28 U.S.C. §§ 1331, 1441, 1442(a)(1) and 1446**

addressed as follows:

Warren R. Paboojian, Esq.
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Counsel for Plaintiffs

[X] By CM/ECF ELECTRONIC DELIVERY: In accordance with the registered case participants and in accordance with the procedures set forth at the Court's website www.ecf.cacd.uscourts.gov.

[X] STATE: I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on **June 1, 2021** at San Diego, California.

F. Villalpando
Felicia Villalpando